IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

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LONNIE CASTO, JANICE WELLMAN, SANDRA SIMMONS, on behalf of herself and as personal representative of the ESTATE OF WHANNA MCQUAIN, MONIE LAYNE, MERRILL NESTER, CLYDE SISSLER, EDGAR FREDWELL, THURMA GRIFFITH, FRANCIS HARDY, BILLY HAY, JAMES HUDDLESTON, KAY JOHNSON, HENRY KENUAM, KATHY KLOPSTEIN, ELIDA KRAJA, TERRY LAMBERT, ELLA MAE MOSELY, CLARA MILAM, ALLEN RAY, WILLIE MAE PEAGLER, SAM SANTANGELO, THOMAS HALCOMB, JACK HOFFMAN, NORMAN INGRASSIA, PEGGY MOORE, PAT NEWELL, DARLENE METZ, CHARLES JACKSON, on behalf of himself and as personal representative of the ESTATE OF MILDRED JACKSON, HARRY BERMAN, HARRY FULTZ, SANDRA RUSSELL, and WILLIS RANTZ

Plaintiffs,

vs.

BAYER PHARMACEUTICALS CORPORATION,
Serve: CT Corporation System
120 South Central Avenue
Clayton, MO 63105

Defendant.

052-8143

Rw1

Case No.

JURY TRIAL DEMANDED

SCANNED
NOV 17 2005
U.S. DISTRICT COURT MPLS

PETITION

INTRODUCTION

1. This is a personal injury proceeding brought on behalf of Plaintiffs who have been injured by the use and ingestion of the prescription medication Baycol. This action seeks, among

DEFENDANT'S EXHIBIT
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Nester suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

7. Plaintiff Clyde Sissler is an individual residing in the State of West Virginia. Mr. Sissler was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Sissler suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

8. Plaintiff Edgar Fredwell is an individual residing in the State of Missouri. Mr. Fredwell was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Fredwell suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

9. Plaintiff Thurma Griffith is an individual residing in the State of Missouri. Ms. Griffith was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Griffith suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

10. Plaintiff Francis Hardy is an individual residing in the State of Missouri. Mr. Hardy was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Hardy suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

11. Plaintiff Billy Hay is an individual residing in the State of Missouri. Mr. Hay was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Hay suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

12. Plaintiff James Huddleston is an individual residing in the State of Missouri. Mr. Huddleston was prescribed and ingested Baycol. As a result of the conduct described below, Mr.

other relief, compensation for the pain and suffering, medical expenses and economic losses of the Plaintiffs.

PLAINTIFFS

2. Plaintiff Lonnie Casto is an individual residing in the State of West Virginia. Mr. Casto was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Casto suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

3. Plaintiff Janice Wellman is an individual residing in the State of West Virginia. Ms. Wellman was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Wellman suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

4. Plaintiff Sandra Simmons is the personal representative of the estate of Whanna McQuain. Whanna McQuain was an individual residing in the State of West Virginia. Ms. McQuain was prescribed and ingested Baycol. As a result of the conduct described below, Ms. McQuain suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

5. Plaintiff Monie Layne is an individual residing in the State of West Virginia. Ms. Layne was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Layne suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

6. Plaintiff Merrill Nester is an individual residing in the State of West Virginia. Mr. Nester was prescribed and ingested Baycol. As a result of the conduct described below, Mr.

Huddleston suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

13. Plaintiff Kay Johnson is an individual residing in the State of Missouri. Ms. Johnson was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Johnson suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

14. Plaintiff Henry Kenuam is an individual residing in the State of Missouri. Mr. Kenuam was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Kenuam suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

15. Plaintiff Kathy Klopstein is an individual residing in the State of Missouri. Ms. Klopstein was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Klopstein suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

16. Plaintiff Elida Kraja is an individual residing in the State of Missouri. Ms. Kraja was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Kraja suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

17. Plaintiff Terry Lambert was an individual residing in the State of Missouri. Mr. Lambert was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Lambert suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

18. Plaintiff Ella Mae Mosely is an individual residing in the State of Missouri. Ms. Mosely was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Mosely suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

19. Plaintiff Clara Milam is an individual residing in the State of Missouri. Ms. Milam was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Milam suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

20. Plaintiff Allen Ray is an individual residing in the State of Missouri. Mr. Ray was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Ray suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

21. Plaintiff Willie Mae Peagler is an individual residing in the Commonwealth of Pennsylvania. Mr. Peagler was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Peagler suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

22. Plaintiff Sam Santangelo is an individual residing in the Commonweath of Pennsylvania. Mr. Santangelo was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Santangelo suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

23. Plaintiff Thomas Halcomb is an individual residing in the State of Ohio. Mr. Halcomb was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Halcomb suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

24. Plaintiff Jack Hoffman is an individual residing in the State of Ohio. Mr. Hoffman was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Hoffman suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

25. Plaintiff Norman Ingrassia is an individual residing in the State of Ohio. Mr. Ingrassia was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Ingrassia suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

26. Plaintiff Peggy Moore is an individual residing in the State of Ohio. Ms. Moore was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Moore suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

27. Plaintiff Pat Newell is an individual residing in the State of Ohio. Ms. Newell was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Newell suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

28. Plaintiff Darlene Metz is an individual residing in the State of Ohio. Ms. Metz was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Metz suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

29. Plaintiff Charles Jackson is the personal representative of the estate of Mildred Jackson. Mildred Jackson was an individual residing in the State of Oklahoma. Ms. Jackson was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Jackson

suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

30. Plaintiff Harry Berman is an individual residing in the State of West Virginia. Mr. Berman was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Berman suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

31. Plaintiff Harry Fultz is an individual residing in the State of West Virginia. Mr. Fultz was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Fultz suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

32. Plaintiff Sandra Russell is an individual residing in the State of West Virginia. Ms. Russell was prescribed and ingested Baycol. As a result of the conduct described below, Ms. Russell suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

33. Plaintiff Willis Rantz is an individual residing in the State of Oklahoma. Mr. Rantz was prescribed and ingested Baycol. As a result of the conduct described below, Mr. Rantz suffered grievous bodily injury and incurred significant expenses as the result of the ingestion of Baycol.

34. Defendant Bayer Pharmaceuticals Corporation has its principal place of business at 100 Bayer Road, Pittsburgh, PA 15205, and is incorporated under the laws of Pennsylvania. At all times relevant hereto, Bayer Pharmaceuticals Corporation was engaged in the business of marketing and distributing Baycol in the United States. Bayer Pharmaceuticals Corporation is hereinafter referred to as "Bayer").

JURISDICTION AND VENUE

35. The Circuit Court of the City of St. Louis, State of Missouri, has jurisdiction over this action and venue is proper because Defendants engage in business in the State of Missouri and derive substantial revenues from this State, and the causes of action alleged herein arose, in part, in the City of St. Louis.

FACTUAL BACKGROUND

Baycol

36. At all times relevant, Defendant, either by itself, or by use of others, did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, advertise, warn, and otherwise distribute in interstate commerce, the product Baycol.

37. Baycol is a member of a class of drugs known as statins that work to inhibit an enzyme in the liver which generates the kind of cholesterol that can clog blood vessels. Statins are commonly prescribed for high blood pressure and heart disease.

38. The cholesterol-lowering drug market is enormous, and Bayer viewed Baycol as a blockbuster product with significant projected growth potential.

39. Bayer introduced Baycol in the U.S. in 1997 after gaining the approval of the United States Food and Drug Administration ("FDA") and marketed it as a safe and effective statin. Baycol was a relatively late entrant into the statin market, and was no more effective at the recommended dose than its competitors. Because it had no efficacy advantage, Bayer pushed for FDA approval of higher dosages of the drug, despite clinical indications that adverse effects were significantly linked to higher doses in clinical trials.

40. Muscle weakness and Rhabdomyolysis are side effects, to varying extent, of all statins. Rhabdomyolysis is a very serious condition in which skeletal muscle tissue is broken

down, releasing muscle enzymes and electrolytes from inside the muscle cells which can cause muscle breakdown, kidney failure and death. The association with Rhabdomyolysis is approximately ten times stronger in Baycol than in other statins, but defendants, and each of them, never adequately warned the FDA, doctors, or consumers of the true risks of the drug.

41. Baycol and gemfibrozil were often jointly administered because Baycol can lower total cholesterol while gemfibrozil can improve the important balance of triglycerides and HDL, or "good," cholesterol. The dual prescription was particularly common for patients with diabetes.

42. The first death from Rhabdomyolysis among Baycol patients was in 1998, within a year of the drug's launch. Since that time, at least 31 additional deaths in this country have been associated with the drug, and the number of deaths caused by Baycol continues to escalate. Bayer has confirmed that over 1,000 cases of muscle weakness and/or damage have been reported in association with the drug. It is believed that far more instances of serious side effects caused by Baycol have occurred but have not yet been properly diagnosed, or associated with taking Baycol. By the end of October 2000, doctors had reported 482 cases of Rhabdomyolysis among Baycol users worldwide. In about half of these cases, the victims had taken Baycol and gemfibrozil.

43. The long-term consequences of Rhabdomyolysis can include muscle tissue degeneration, damage to the kidneys, liver lesions, and damage to other major organs. All of these effects can occur without any marked outward symptoms, or without any symptoms that would be recognized as associated with Baycol or with Rhabdomyolysis by a doctor not specifically looking for that connection.

44. In January, 1999 the FDA required certain changes in Baycol labeling. In the Warnings section, under Skeletal Muscle, the test was revised to read, "Rare cases of Rhabdomyolysis (some with acute renal failure secondary to myoglobinuria) have been reported with cerivastatin and other drugs in this class." In addition, under the adverse reactions section, the following language was added, "The following events have been reported since market introduction. While these events were temporally associated with the use of Baycol, a causal relationship to the use of Baycol cannot be readily determined due to the spontaneous nature of reporting of medical events, and the lack of controls; hepatitis, myositis, Rhabdomyolysis, some with associated renal failure (most cases involved concomitant gemfibrozil), urticaria, angioedema, visual disturbance, blurred vision."

45. In the face of mounting evidence from post-marketing experience, and given data from clinical trials, Bayer knew or should have known that a significant portion of the adverse effects experienced were causally related to Baycol use. Bayer had knowledge of studies measuring the levels of certain enzymes indicating the destruction of muscle and liver cells. These studies showed significant increases in enzyme levels. These results were found in healthy young test subjects who had taken Baycol. The studies showed that higher dosages of Baycol led to even higher enzyme levels in a greater number of test subjects.

46. Despite these clinical trials and the experience of patients, Bayer persisted in seeking approval of higher dosages. In May, 1999, four months after requiring the labeling change, the FDA granted approval to market a .4 mg dose, double the previous highest dose. Unsatisfied, Bayer pushed on to get approval of a .8 mg dose.

47. The further testing required for the new dose should have signaled significant problems with the .4 mg dose, and an even higher rate of adverse events for groups taking a .8

mg dose of Baycol. Significant numbers of test subjects dropped out of these tests with Rhabdomyolysis-related symptoms. Of the remaining subjects, incidence of enzyme levels indicated significant muscle and liver cell damage in a high percentage of patients. Nevertheless, Bayer moved ahead with its plans, and received approval to market the .8 mg dose in July, 2000.

48. In late 2000, the German health ministry became sufficiently concerned with reported adverse effects that it put the drug on a watch list.

49. In April 2000, the FDA again mandated stronger label warnings, in particular emphasizing the risks of prescribing gemfibrozil in conjunction with Baycol. On May 21, 2001, Bayer sent doctors a "Dear Doctor" letter which belatedly called attention to some of the dangers associated with Baycol use, particularly when combined with gemfibrozil. Nonetheless, Bayer continued to misrepresent and conceal the dangers associated with Baycol. Still the company insisted, "When used as directed, Baycol effectively and safely treats patients with [high cholesterol levels]."

50. These warnings were ineffective both because they were simply insufficient to prevent co-prescription of Baycol with gemfibrozil, and because Baycol was associated with a significant number of adverse events even if prescribed alone. Indeed, most of the deaths in the United States occurred in patients who were not taking gemfibrozil.

51. Despite its knowledge of the ineffectiveness of its warnings, and of the dose-dependent and inherent dangers of Baycol use, Bayer continued to conceal the adverse effects associated with Baycol use and to market the drug throughout the United States and abroad. Bayer marketed both the .4 mg and the .8 mg doses to doctors as safe and highly effective. There was no balance in the advertisements between the statements of efficacy, large and prominent,

and the statements of risk and danger, embedded in lengthy fine print statements, misleading in their presentation.

52. On August 8, 2001, Bayer announced that it was removing Baycol from the market for public safety reasons. At the same time it finally revealed the damages associated with Baycol by issuing a letter to doctors, now stating that "Rhabdomyolysis is a serious, potentially fatal, adverse effect of all statin drugs, including Baycol. It can occur with statin monotherapy, though the risk appears to be increased significantly by concomitant use of gemfibrozil (Lopid)."

53. In July, the European Medicines Evaluation Agency announced that it was investigating the side effects of Baycol.

54. The German health ministry has accused Bayer A.G. of grave errors in its information policy regarding the side effects of Baycol. The company is reported to have withheld new information on the side effects from the German institute for drugs and medical products for almost two months and only made the information available on demand. Under German drug law, new information over serious side effects must be reported within 15 days. Nonetheless, Bayer continued to misrepresent and conceal the dangers associated with Baycol. Still the company insisted, "When used as directed, Baycol effectively and safely treats patients with [high cholesterol levels.]"

55. Worldwide, six million patients have been treated with Baycol. Some 700,000 patients are estimated to have taken the drug in the U.S. Last year Bayer's Baycol sales exceeded $550 million. This year Bayer had predicted significant growth in sales.

Defendant's Malice

56. The conduct of Bayer, as described in paragraphs 1-55, as well as in the specific legal claims set out below, was outrageous due to its evil motive and reckless indifference to the rights of others. Defendant Bayer acted with malice, and its conduct was willful, wanton, and malicious, and demonstrated both complete indifference and conscious disregard for the safety of others.

COUNT I
Strict Liability - Defective Design

57. Plaintiffs incorporate by this reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

58. Defendant Bayer was the manufacturer and/or supplier of Baycol.

59. Defendant Bayer did in fact sell, distribute, supply, manufacturer and/or promote Baycol to Plaintiffs and their prescribing physicians. Defendant intended Baycol to reach and it did in fact reach, Plaintiffs' prescribing physicians and Plaintiffs without substantial change in the condition.

60. Baycol, as sold, distributed, supplied, manufactured and/or promoted by Bayer, was in a defective and unreasonably dangerous condition at the time it was placed into the stream of commerce by Defendant in ways which include, but are not limited to, one or more of the following particulars:

a. Baycol contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of the drug;

b. Baycol was defective in design and formulation, making use of the drug more dangerous than the ordinary consumer would expect, and more dangerous than other risks associated with elevated cholesterol;

c. Baycol contained insufficient and/or incorrect warnings to alert consumers and users of the risks of adverse effects;

d. Baycol was not distributed with up-to-date package inserts (labels);

e. Baycol was not safe for its intended use as a cholesterol-lowering medication;

f. Baycol was inadequately tested;

g. Baycol was defective in design or formulation, in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, and was more dangerous than an ordinary consumer would expect, and more dangerous than other forms of cholesterol reduction;

h. Baycol was defective due to inadequate post-marketing warning or instruction because after Defendant knew, or should have known, of the risk of injury from Baycol, prescribed independently or in combination with gemfibrozil, it failed to provide adequate warnings to users or consumers of the product and continued to promote the product; and

i. Baycol was not accompanied by adequate instructions and/or warnings to fully apprise the prescribing physicians, as well as the ultimate users, including Plaintiffs, of the full nature or extent of the risks and side-effects associated with its use.

61. Plaintiffs used the drugs for their intended purpose, i.e., elevated cholesterol treatment.

62. As a direct and proximate result of the defective and unreasonably dangerous condition Plaintiffs were injured in and about their bodies, or aggravated pre-existing conditions or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of their injuries, suffered physical handicap, suffered psychological and emotional injuries, sustained permanent injuries with a reasonable degree of medical probability up to and including death, and/or suffered permanent loss of an important bodily function, suffered increased risk and susceptibility to like or related injury in the future, and suffered permanent impairment of the capacity for the enjoyment for life.

63. Since the injuries suffered by Plaintiffs are continuing in nature, they will continue to suffer pain, psychological and emotional injuries, physical handicaps and permanent injuries in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

64. Plaintiffs have also sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown

65. Defendant showed complete indifference to, or conscious disregard for, the safety of others when it knowingly introduced Baycol into commerce with knowledge of its aforestated defects, and therefore, awards of punitive damages are warranted.

66. This count is brought on behalf of all Plaintiffs. More specifically, this count is brought pursuant to W.Va. Code §55-7-8a (2005) (on behalf of the estate of Whanna McQuain), and pursuant to 12 Okl. St. §1051 (2004) (on behalf of the estate of Mildred Jackson.)

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants for:

a. Actual and compensatory damages in an amount to be proved at trial;

b. Costs of suit;

c. Pre-judgment and post-judgment interest;

d. Punitive damages in a fair and reasonable amount to punish and deter Defendant and others from engaging in the same wrongful conduct; and

e. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT II
Strict Liability - Failure To Warn

67. Plaintiffs incorporate by this reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

68. Defendant has engaged in the business of selling, distributing, supplying, manufacturing, marketing and/or promoting Baycol and through that conduct have knowingly and intentionally placed Baycol into the stream of commerce.

69. Defendant did in fact sell, distribute, supply, manufacture and/or promote Baycol to Plaintiffs, and their prescribing physicians. Additionally, Defendant expected the Baycol it was selling, distributing and supplying, manufacturing and/or promoting to reach, and the Baycol did in fact reach consumers and their prescribing physicians, without substantial change in the condition.

70. At all times material hereto, Baycol was sold, distributed, supplied, manufactured, marketed, and/or promoted by Defendant in a manner which failed to adequately warn about the dangers this drug posed to consumers. Examples of the inadequacy of Defendant's warnings include, but are not limited to, one or more of the following particulars:

a. Baycol contained warnings insufficient to alert Plaintiffs and/or their physicians, to the risks of adverse reactions associated with the drug, subjecting Plaintiffs to risks which exceeded the benefits of the drug;

b. Baycol contained misleading warnings - emphasizing the efficacy of the drug, while down playing the risks associated with it - thereby making use of the drug more dangerous than the ordinary consumer would expect, and more dangerous than other risks associated with elevated cholesterol;

c. Baycol contained insufficient and/or incorrect warnings to alert consumers, and their prescribing physicians, to the risk, scope, duration and severity of the adverse reactions associated with the drug;

d. Baycol did not disclose that it was inadequately tested;

e. the Baycol label did not disclose that the drug, used alone or in combination with gemfibrozil, posed an increased greater risk of adverse reaction as dosage was increased;

f. Baycol did not adequately warn against the combination use of Baycol and gemfibrozil the drugs and the dangers presented thereby;

g. Baycol failed to convey adequate post-marketing warnings regarding the risk, severity, scope and/or duration of the dangers posed by the drugs used alone or in combination;

h. Baycol failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers;

i. Baycol failed to warn consumers and their physicians that its "potency" in correspondingly lower dosage levels would not reduce the risk of adverse events associated with its use; and

j. Baycol misrepresented that its dual metabolic pathway mechanism of action would reduce the number of adverse drug-drug interactions, when in fact users were more likely to suffer an adverse event when taking Baycol in combination with gemfibrozil, and users of gemfibrozil and any other statin.

71. Plaintiffs used the drugs for their intended purpose, i.e., elevated cholesterol treatment.

72. As a direct and proximate result of the defective and unreasonably dangerous condition of Baycol, used alone and/or in combination, as aforesaid, Plaintiffs were injured in and about their bodies, or aggravated pre-existing conditions or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of their injuries, suffered physical handicap, suffered psychological and emotional injuries, sustained permanent injuries with a reasonable degree of medical probability, up to and including death and/or suffered permanent loss of an important bodily function, suffered increased risk and susceptibility to like or related injury in the future, and suffered permanent impairment of the capacity for the enjoyment for life.

73. Since the injuries suffered by Plaintiffs are continuing in nature, they will continue to suffer pain, psychological and emotional injuries, physical handicaps and permanent injuries in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

74. Plaintiffs have also sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown.

75. Defendant showed complete indifference to, or conscious disregard for, the safety of others when they knowingly introduced Baycol into commerce with knowledge of their afore stated defects.

76. This count is brought on behalf of all Plaintiffs. More specifically, this count is brought pursuant to W.Va. Code §55-7-8a (2005) (on behalf of the estate of Whanna McQuain), and pursuant to 12 Okl. St. §1051 (2004) (on behalf of the estate of Mildred Jackson.)

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant for:

a. Actual and compensatory damages in an amount to be proved at trial;

b. Costs of suit;

c. Pre-judgment and post-judgment interest;

d. Punitive damages in a fair and reasonable amount to punish and deter Defendant and others from engaging in the same wrongful conduct; and

e. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT III
Negligence

77. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

78. Defendant owed a duty to the expected consumers of Baycol, to exercise reasonable care in the design, testing, manufacture, sale, promotion and/or distribution of Baycol,

including a duty to take reasonable steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

79. Defendant owed an additional and further duty to provide adequate and complete instructions and warnings:

a. to assist prescribing physicians in the proper administration and prescription of Baycol, alone or in combination with gemfibrozil;

b. to provide adequate and complete warnings and instructions to Plaintiffs sufficient to make them aware of the risks associated with the drugs, the warning signs associated with those risks, and the measures necessary to avoid and/or mitigate those risks; and

c. to promptly amend and supplement such instructions and warnings upon the discovery of information necessitating such amendment and supplement.

80. It was foreseeable that a breach of the aforementioned duties would cause injury and/or related damage to the ultimate consumers of Baycol.

81. Defendant was negligent and breached the aforementioned duties in ways which include, but are not limited to, one or more of the following:

a. failing to exercise reasonable care in the manufacture, sale, testing, quality assurance, quality control, advertising, labeling, promotion and/or distribution of Baycol;

b. failing to fully and/or adequately warn of the nature and scope of the dangers associated with Baycol when taken alone or in combination with gemfibrozil, including the high risk of unreasonable and dangerous side effects;

c. failing to use reasonable care in designing, manufacturing, distributing, and/or promoting Baycol so as to reduce or eliminate the aforementioned risks;

d. failing to provide proper warnings regarding all possible adverse side effects associated with the use of Baycol and the comparative severity and duration of such adverse effects;

e. failing to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Baycol across all dosage levels;

f. failing to provide adequate information, warnings, and/or training to medical care providers regarding the appropriate use of Baycol, and their associated risks;

g. failing to provide warnings or instructions sufficient to alert consumers and physicians about the need for comprehensive, regular medical monitoring to ensure early discovery of, or avoid altogether, potentially fatal adverse effects of Baycol, including, but not limited to, Rhabdoymolysis, kidney failure, heart arrhythmia or failure, and/or peripheral neuropathy;

h. failing to fully and/or adequately warn of the risk, scope, severity, and duration of the dangers associated with the Baycol when used in combination with gemfibrozil.

i. failing to provide consumers and/or their physicians with warnings and/or information sufficient to allow them to evaluate when and whether the use of Baycol, alone or in combination with gemfibrozil, was causing or was increasing the risk of adverse side effects, including, but not limited to,

myopathy, Rhabdomyolysis, peripheral neuropathy, kidney failure, heart arrhythmia or failure, and other debilitating conditions;

j. by placing an unsafe product into the stream of commerce;

k. by failing to timely supplement and/or warn of additional dangers and hazards associated with the use of Baycol, alone or in combination with gemfibrozil, upon the discovery of information necessitating such action;

l. by continuing to market and promote Baycol to prescribing physicians and consumers, and their prescribing physicians, notwithstanding the fact that Defendants knew, or should have known, that Baycol caused serious and permanent injury;

m. by encouraging the misuse and overuse of Baycol, alone or in combination with gemfibrozil, while down-playing its side effects to doctors and the public in order to make a profit from sales; and

n. were otherwise careless or negligent.

82. Despite the fact that Defendant knew, or should have known, that Baycol, alone or in combination with gemfibrozil, caused unreasonable and dangerous side effects which many users would be impotent to remedy by any means, Defendant continued to market Baycol to consumers, when there were safer alternative methods of lowering cholesterol levels.

83. Defendant knew, or should have known, that consumers would foreseeable suffer injury as the result of Defendant's failure to exercise ordinary care as described above.

84. Defendant's negligence was a proximate cause of Plaintiffs' injuries, harm and economic loss which they suffered and will continue to suffer, as previously described.

85. Defendant demonstrated complete indifference to, or conscious disregard for the safety of others, and therefore, are entitled to an award of punitive damages.

86. This count is brought on behalf of all Plaintiffs. More specifically, this count is brought pursuant to W.Va. Code §55-7-8a (2005) (on behalf of the estate of Whanna McQuain), and pursuant to 12 Okl. St. §1051 (2004) (on behalf of the estate of Mildred Jackson.)

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant for:

a. Actual and compensatory damages in an amount to be proved at trial;

b. Costs of suit;

c. Pre-judgment and post-judgment interest;

d. Punitive damages in a fair and reasonable amount to punish and deter Defendant and others from engaging in the same wrongful conduct; and

e. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT IV
Breach of Express Warranty

87. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

88. Defendant expressly warranted that Baycol, when used alone or in combination, was safe and well-tolerated during patient studies.

89. Baycol did not conform to these express representations because Baycol was not safe and has high levels of serious side effects, including life-threatening side effects.

90. As a direct and proximate result of the breach of these warranties, Plaintiffs suffered, and will continue to suffer injury, harm and economic loss, as alleged herein.

91. This count is brought on behalf of all Plaintiffs. More specifically, this count is brought pursuant to W.Va. Code §55-7-8a (2005) (on behalf of the estate of Whanna McQuain), and pursuant to 12 Okl. St. §1051 (2004) (on behalf of the estate of Mildred Jackson.)

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant for:

a. Actual and compensatory damages in an amount to be proved at trial;

b. Costs of suit;

c. Pre-judgment and post-judgment interest;

d. Punitive damages in a fair and reasonable amount to punish and deter Defendant and others from engaging in the same wrongful conduct; and

e. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT V
Breach of Implied Warranty

92. Plaintiffs incorporate by this reference all preceding paragraphs as if fully set forth herein, and further allege as follows.

93. At the time Defendant marketed, sold and distributed Baycol for use by Plaintiffs, Defendant knew of the use for which Baycol was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

94. Plaintiffs, and their physicians, reasonably relied upon the skill and judgment of Defendant as to whether Baycol was of merchantable quality and safe for their intended use.

95. Contrary to such implied warranty, Baycol was not of merchantable quality or safe or fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purpose for which it was used as described above.

96. As a direct and proximate result of the breach of implied warranty, Plaintiffs suffered and will continue to suffer injury, harm and economic losses alleged herein.

97. This count is brought on behalf of all Plaintiffs. More specifically, this count is brought pursuant to W.Va. Code §55-7-8a (2005) (on behalf of the estate of Whanna McQuain), and pursuant to 12 Okl. St. §1051 (2004) (on behalf of the estate of Mildred Jackson.)

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant for:

a. Actual and compensatory damages in an amount to be proved at trial;

b. Costs of suit;

c. Pre-judgment and post-judgment interest;

d. Punitive damages in a fair and reasonable amount to punish and deter Defendant and others from engaging in the same wrongful conduct; and

e. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT VI
Wrongful Death of Whanna McQuain and Mildred Jackson

98. Plaintiffs Sandra Simmons and Charles Jackson, on behalf of themselves and as personal representatives of the estates of Whanna McQuain and Mildred Jackson (respectively) incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

99. This Count stems from personal injuries that were the direct and proximate cause of the death of Whanna McQuain and Mildred Jackson. It is brought by Sandra Simmons (the daughter of Whanna McQuain, pursuant to West Virginia's Wrongful Death Act W.Va. Code §55-7-5(2005)) and Charles Jackson (the husband of Mildred Jackson, pursuant to Oklahoma's Wrongful Death Act 12 Okla. St. §1053 (2004)).

100. Defendant owed a duty to Plaintiffs' Decedents to provide pharmaceutical products reasonably safe in design, production and manufacture; a duty to warn of any dangerous defects or side effects; a duty to assure their products did not cause users unreasonable and dangerous risks, reactions, and side effects; and a duty to correct and/or replace any drugs that are defective or dangerous.

101. Defendants breached each of the above listed duties in that Defendant:

a. failed to exercise reasonable care in the manufacture, sale, testing, quality assurance, quality control, advertising, labeling, promotion and/or distribution of Baycol;

b. failed to fully and/or adequately warn of the nature and scope of the dangers associated with Baycol when taken alone or in combination with gemfibrozil, including the high risk of unreasonable and dangerous side effects;

c. failed to use reasonable care in designing, manufacturing, distributing, and/or promoting Baycol so as to reduce or eliminate the aforementioned risks;

d. failed to provide proper warnings regarding all possible adverse side effects associated with the use of Baycol and the comparative severity and duration of such adverse effects;

e. failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Baycol across all dosage levels;

f. failed to provide adequate information, warnings, and/or training to medical care providers regarding the appropriate use of Baycol, and their associated risks;

g. failed to provide warnings or instructions sufficient to alert consumers and physicians about the need for comprehensive, regular medical monitoring to ensure early discovery of, or avoid altogether, potentially fatal adverse effects of Baycol, including, but not limited to, Rhabdoymolysis, kidney failure, heart arrhythmia or failure, and/or peripheral neuropathy;

h. failed to fully and/or adequately warn of the risk, scope, severity, and duration of the dangers associated with the Baycol when used in combination with gemfibrozil.

i. failed to provide consumers and/or their physicians with warnings and/or information sufficient to allow them to evaluate when and whether the use of Baycol, alone or in combination with gemfibrozil, was causing or was increasing the risk of adverse side effects, including, but not limited to, myopathy, Rhabdomyolysis, peripheral neuropathy, kidney failure, heart arrhythmia or failure, and other debilitating conditions;

j. placed an unsafe product into the stream of commerce;

k. failed to timely supplement and/or warn of additional dangers and hazards associated with the use of Baycol, alone or in combination with gemfibrozil, upon the discovery of information necessitating such action;

l. continued to market and promote Baycol to prescribing physicians and consumers, and their prescribing physicians, notwithstanding the fact that Defendant knew, or should have known, that Baycol caused serious and permanent injury;

m. encouraged the misuse and overuse of Baycol, alone or in combination with gemfibrozil, while down-playing its side effects to doctors and the public in order to make a profit from sales; and

n. were otherwise careless or negligent.

102. Defendant should have known that Baycol caused unreasonably dangerous risks and serious side effects of which the general public would not be aware. Defendant nevertheless advertised, marketed, prescribed, licensed and promoted Baycol knowing there were safer methods and products for cholesterol control.

103. As a direct and proximate result of the negligence and carelessness of Defendant Whanna McQuain and Mildred Jackson sustained personal injuries causing death. As a result, Plaintiffs sustained pecuniary losses by reason of their death, funeral expenses, medical expenses, loss of services, consortium, companionship, comfort, instruction, guidance, counsel, training and support for which they seeks recovery.

104. Plaintiffs also seek such damages as Plaintiffs' decedents suffered between the time of injury and the time of death for which Whanna and Mildred might have maintained an action had death not ensued.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant for:

a. Actual and compensatory damages in an amount to be proved at trial;

b. Costs of suit;

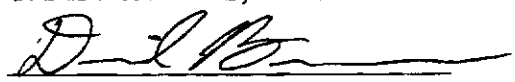
c. Pre-judgment and post-judgment interest;

d. Punitive damages in a fair and reasonable amount to punish and deter Defendant and others from engaging in the same wrongful conduct; and

e. Such other and further relief as the Court deems just and proper under the circumstances.

Respectfully submitted,

CAREY & DANIS, L.L.C.

By: 

John J. Carey, MO Bar #36918
David W. Bauman MO Bar #52481
8235 Forsyth, Suite 1100
St. Louis, MO 63105
Telephone: (314) 725-7700
Facsimile: (314) 721-0905

Attorneys for Plaintiffs

MISSOURI CIRCUIT COURT

TWENTY-SECOND JUDICIAL CIRCUIT

(St. Louis City)

LONNIE CASTO

PETITIONER/PLAINTIFF

VS

BAYER PHARACEUTICALS CORPORATION

RESPONDENT/DEFENDANT

NO.052-08113

SUMMONS DIV. 01

THE STATE OF MISSOURI TO DEFENDANT:

YOU ARE HEREBY SUMMONED TO APPEAR BEFORE THE ABOVE NAMED COURT AND TO FILE YOUR PLEADING TO THE PETITION, COPY OF WHICH IS ATTACHED HERETO, AND TO SERVE A COPY OF YOUR PLEADING UPON ATTORNEY BAUMAN, DAVID W
FOR THE PETITIONER WHOSE ADDRESS IS
8235 FORSYTH SUITE 1100, CLAYTON, MO 63105-

ALL WITHIN 30 DAYS AFTER SERVICE OF THIS SUMMONS UPON YOU, EXCLUSIVE OF THE DAY OF SERVICE. IF YOU FAIL TO DO SO, JUDGEMENT BY DEFAULT WILL BE TAKEN AGAINST YOU FOR THE RELIEF DEMANDED IN THE PETITION .

WITNESS, MARIANO V. FAVAZZA, CLERK OF SAID COURT, WITH THE SEAL THERE OF HEREUNTO AFFIXED, AT ST. LOUIS, MISSOURI, THIS 16TH DAY OF AUGUST, 2005 .

FILE

MARIANO V. FAVAZZA Circuit Clerk

Sheriff of ST LOUIS COUNTY

CIVIL 1

No. 052-08113
Div. 01

SUMMONS

In the case of

LONNIE CASTO

PLAINTIFF

Vs.

BAYER PHARACEUTICALS CORPORATI
ON

DEFENDANT

BAYER PHARACEUTICALS CORPORATI
ON

SERV

CT CORPORATION SYSTEM
120 SOUTH CENTRAL AVENUE

CLAYTON MO 63105